

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. 09/807,402  
Applicant : Hofert et al.  
Filed : August 3, 2001  
Title : COMBINATION OF GESTAGENS AND SUGARS  
TC/A.U. : 1623  
Examiner : L. C. Maier  
Attny. Docket No. : SCH-1808



**REPLY BRIEF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Further to the Examiner's Answer mailed on August 11, 2006, please consider the following.

The Examiner's Answer on the top of page 6 alleges that "appellant has conflated the ideas of "expectation" with that of "prediction." Appellants disagree. Moreover, appellants maintain that there is nothing in the prior art that teaches or suggests at all that the claimed combination would lead to the unexpected results of stabilization from acyloin rearrangement.

As discussed in the Appeal Brief, nothing in the prior art teaches that the gestagen of formul I, having a  $\alpha$ -hydroxy side chain, which gives rise to an acyloin rearrangement when the claimed gestagens are stored, can be stabilized from such acyloin rearrangement. Whether one of ordinary skill in the art would have expected stabilization of steroids generally from oxidation based on the teachings of Backensfeld, either in a low-dose composition or not in a composition, is irrelevant to whether one of ordinary skill in the art would have expected the stabilization of the gestagen of formula I from acyloin rearrangement. Such stabilization is unexpected.

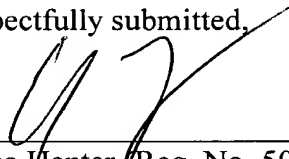
Appellants additionally have submitted data that demonstrates for the reasons already discussed that the stabilization from acyloin rearrangement is significant. This data, although believed to be unnecessary for the patentability of the claimed invention, is adequate to

overcome the alleged general motivation of the prior art to combine steroidal sex hormones with cyclodextrins to prevent the oxidation thereof.

Reversal of the rejection is respectfully and courteously requested.

The Commissioner is hereby authorized to charge any fees associated with this Brief or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



---

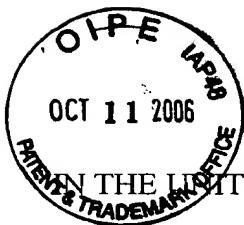
Csaba Henter (Reg. No. 50,908)  
Brion P. Heaney (Reg. No. 32,542)  
Attorneys for Applicant(s)

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: Sch-1808

Date: October 11, 2006

K:\Sch\1808\Reply Brief.doc



UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/807,402  
Applicant : Hofert et al.  
Filed : August 3, 2001  
Title : COMBINATION OF GESTAGENS AND SUGARS  
TC/A.U. : 1623  
Examiner : L. C. Maier  
Attny. Docket No. : SCH-1808

**APPEAL BRIEF (AMENDED)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Further to the Notification of Non-Compliant Appeal Brief mailed on September 11, 2006, and further to the Notice of Appeal filed on February 1, 2006, please consider the following.

The first reason for the Notification of Non-Compliant Appeal Brief is that "the brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper headings or in the proper order." Appellants respectfully disagree. The Brief contained all the required items with the proper headings and in the proper order. The only thing applicants think may have been the cause of this basis for the Notification is that the items were numbered from "(i)" to "(x)" in the same way as they are numbered in 37 CFR 41.37(c). This numbering of items is now removed.

The other bases for the Notification are overcome by the amendments to the Appeal Brief.

No substantive changes were made to the Appeal Brief other than those issues specifically raised by the Notification.

The Commissioner is hereby authorized to charge any fees associated with this Brief or credit any overpayment to Deposit Account No. 13-3402.